

### REMARKS

Claims 29 and 43-59 are rejected under 35 USC 102(b) as being anticipated by Kidd (US 5,829,441), while claims 30-42 would be allowable if rewritten to incorporate the features of independent claim 29. By this response, original claims 29, 30, 32, 46 and 57 - 59 have been amended, while new claims 60 and 61 have been added.

The dental device disclosed in Kidd includes adjustable upper and lower arch trays and a coupling configured to pull the lower jaw of a user forwardly during sleep to minimize snoring and mild apnea conditions. The coupling can be adjusted while the device is in the patient's mouth, to insure the most comfortable fit consistent with lower jaw extension. Each arch tray includes a pair of diverging leg members that are integrally formed into their respective arch trays. Adjustment slots are formed in the arch trays to define joints. Unfortunately, the construction of the device of Kidd includes numerous deficiencies (all of which have been rectified by the claimed invention) renders it usable in only about 20% of all patients. By contrast, the instant device, while having individual elements that bear some structural similarity to Kidd, has numerous distinguishing features that render it patentably distinct therefrom. For example, the now-claimed angular adjustability of the extension members of the splint of the present invention allows the front of the device to adopt different angular curvatures at the front of the mouth, and also to hinge about the ends of the fastener so as to be able to more closely follow the exact curvature of a patient's mouth, particularly along the sides of the mouth. As there are no lines of weakness, the extension members of the present invention can be articulated without breaking. Also, when the molded material of the splint of the present invention is cooled there is little or no tendency for the extension members to return to their original position, since the hinge allows greater movement and forms a point of articulation at the hinge rather than relying on the inherent deformability of the material to maintain the correct orientation with little assistance from the slots. One of the major problems with the unitary structure of the device disclosed in Kidd is that when the ends of the splint members were bent or otherwise moved, almost invariably the arch members would break along the lines of weakness caused by the slots.

Another shortcoming with the device disclosed in Kidd that is overcome by the claimed invention is that the range of variability of the shapes that the splint could adopt is considerably reduced due to the inherent resiliency of the material from which the arch member was made. Such material has a memory causing the material, particularly when softened, to adopt its original position. Yet another distinction between the device of Kidd and the claimed invention is that with the former, in addition to the difficulty in bending the splint there is no way to reduce the length of the splint side members. Since many patients need shorter members to overcome occlusions and clearance problems, those fitted with the Kidd device could not close their mouth owing to the length of the sides of this form of the splint. Moreover, the presence of the slots made it difficult to accurately reduce the length of the sides of the splint. The claimed device overcomes this problem by having snap-off segments located at spaced apart locations along the extension members. By bending the extension members about the selected snap line the length of the extension member could be adjusted by snapping off of the excess length, thereby providing a more custom fit.

Most patients have a mouth with a shape that does not allow the slot type arch member to bend sufficiently to conform to the individual's mouth shape. This is true for the front of the mouth in the region where the adjuster of Kidd is located, since the adjuster itself cannot bend due to the particular construction of the Kidd device. The length of the wings (extension members) of the Kidd construction also prohibits their being curved around sufficiently to conform to the radius of curvature of the mouth. Recourse in Kidd to additional slots so that the extensions can be curved more sharply (to, for example, emulate the angularly adjustable features of the claimed hinge-based extension members) is unavailing, as these additional lines of weakness make the already fragile device even more prone to breakage. Yet another problem associated with the Kidd device is that it incorporates small screws to hold the upper arch member to the fastener. These screws can become loose during use of the device, thereby presenting a danger that a patient could swallow the screws. As the device of the present invention is provided with wings or side extensions on either side having holes through which the softened material of the extension pieces can flow, there is no need for separate screws to hold the fastener to the extension pieces. Additionally, a major problem and clinically dangerous situation with the Kidd design was the offset of the adjuster screw and the screw stop at the back.

A frequent concomitant to people with snoring problems and sleep apnea is the grinding of teeth in such patients. Patients using the Kidd design and who experienced teeth grinding put forces on the device that caused the screw to break away from the housing. This problem is totally overcome by the adjuster screw being enclosed in the housing of the present device.

For all of the above reasons, the Applicant submits that claims 29 - 61 of the application are patentably distinct over the device disclosed in Kidd, and as such are now in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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